

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Schuler et al.	Group Art Unit: 3773
Application No: 10/601,127 Confirmation No: 5998	Examiner: Erez, Darwin P.
Filed: June 19, 2003	Attorney Docket No: 53243-US-CNT[2] (NV.0047.10)
Title: SYSTEMS AND METHODS FOR AEROSOLIZING PHARMACEUTICAL FORMULATIONS	October 5, 2010 San Francisco, California 94107

**REPLY BRIEF**

*VIA ELECTRONIC FILING*

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Examiner:

In response to the Examiner's Answer mailed on August 5, 2010, the Applicant of the above-referenced patent application (hereinafter Appellant) hereby maintains the appeal to the Board of Patent Appeals and Interferences. Appellant requests the reversal of the Final Rejection.

**Certificate of Transmission**

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, facsimile transmitted to the U.S. Patent and Trademark Office at (571) 273-8300, or electronically submitted via EFS on the date shown below:

By:

  
Melanie Hitchcock

Date: October 5, 2010

### ***Status of Claims***

Claims 53-60 are presently pending in the case. Claims 53-60 have been finally rejected. The rejection of each of claims 53-60 is hereby appealed.

Claims 1-52 have been cancelled.

***Grounds of Rejection to be Reviewed on Appeal***

Appellant continues to request review of the Examiner's following grounds of rejection:

Claims 53-55, 57 and 59 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 5,727,546 to Clarke et al (hereinafter Clarke et al).

Claim 56 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Clarke et al.

Claims 58 and 60 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Clarke et al in view of U.S. Patent 6,116,237 to Schultz et al (hereinafter Schultz et al).

Applicant also now requests review of the following new ground of the rejection made in the Examiner's Answer of August 5, 2010:

Claim 60 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Clarke et al in view of U.S. Patent 5,724,959 to McAughey et al (hereinafter McAughey et al).

## **Argument**

Appellant believes each of claims 53-60 is improperly rejected and is therefore allowable for the reasons set forth in Appellant's Appeal Brief filed on September 10, 2009. The present Reply Brief is being filed to specifically address the new rejection raised by the Examiner in the Examiner's Answer mailed on August 5, 2010 and new issues raised in the Examiner's Answer. The comments herein are merely supplemental to the arguments made in the Appeal Brief and are not meant to replace those arguments.

### The new rejection under §103(a) is improper

The new rejection of claim 60 under 35 U.S.C. §103(a) as being unpatentable over Clarke et al in view of McAughey et al is improper and should be reversed.

Claim 60 depends from independent claim 53. Claim 53 is not rendered unpatentable by Clarke et al for the reasons set forth in the Appeal Brief of September 10, 2009. McAughey et al is not relied upon to make up for the deficiencies of Clarke et al with respect to claim 53, nor does it. Accordingly, independent claim 53 is allowable over the combination of Clarke et al and McAughey et al, and since claim 60 depends from claim 53, it too is allowable over the references. Reversal of the rejection is requested.

### Examiner's Response to Argument

The Examiner's comments in the Examiner's Answer of August 5, 2010 do not serve to establish Clarke et al as an anticipatory reference of claim 53 under 35 U.S.C. §102(b).

More specifically, on page 9, lines 5-20 of the Examiner's Answer, the Examiner justifies the rejection by explaining a misconstrued interpretation of the claim language

“when the respiratory gases are permitted to flow.” According to the Examiner, the recited claim language does not mean the same as “when the respiratory gases are first permitted to flow” (page 9 line 11). Appellant contends the Examiner is not affording the limitation its proper meaning.

In the context of the claim, particularly in view of the specification, one of ordinary skill in the art would understand the intended meaning of the expression to be when the respiratory gases are first permitted to flow. In actuality, the use of the term “first” would be redundant because of the presence of the word “permitted.” It follows then that the following two expressions are equivalent:

- (1) “when the respiratory gases are permitted to flow” and
- (2) “when the respiratory gases first flow.”

To better explain the point by counterexample, it should be noted that a hypothetical expression “when the gases are flowing” could mean at any time when gases are flowing. However, “when the gases are permitted to flow” means at the point of being permitted to flow, which, in the present context, is when the gases are first flowing. Further making the point by way of analogy, “when the dam broke” would mean at the point in time when the dam broke, not two days later when water continues to flow over the broken dam.

Semantic juggling notwithstanding, one of ordinary skill in the art would understand that the claim 53 recitation at issue relates to a structural feature of the disclosed regulator. The disclosed and claimed structural feature is different than the valve of Clarke et al, despite the Examiner’s attempts to squeeze Clarke et al’s square peg into Appellant’s claimed round hole.

## Conclusion

Thus, it is believed that all rejections made by the Examiner have been addressed and overcome by the above arguments and the arguments provided in the Appeal Brief. Therefore, all pending claims are allowable. A reversal is respectfully requested.

Should there be any questions, Appellant's representative may be reached at the number listed below.

Respectfully submitted,

JANAH & ASSOCIATES

Dated: October 5, 2010

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